



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0530]

Draft Guidance for Industry and Food and Drug Administration Staff; Medical Devices: The Pre-Submission Program and Meetings with FDA Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled “Medical Devices: The Pre-Submission Program and Meetings with FDA Staff.” The purpose of this guidance is to describe the Pre-Submission program (formerly the pre-Investigational Device Exemption (IDE) program) for medical devices reviewed in the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER). In addition, the guidance provides recommendations regarding information that should be included in a Pre-Submission Package. This guidance also describes the procedures that CDRH and CBER intend to follow when industry representatives or application sponsors request a meeting with review staff. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS ADFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit either written or electronic comments on this collection of

information by [INSERT DATE 60 DAYS ADFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled “Medical Devices: The Pre-Submission Program and Meetings with FDA Staff” to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002; or Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Angela Krueger,
Center for Devices and Radiological Health,
Food and Drug Administration,
10903 New Hampshire Ave.,
Bldg. 66, rm. 1666,
Silver Spring, MD 20993-0002,

301-796-6380; or Stephen Ripley,
Center for Biologics Evaluation and Research (HFM-17),
Food and Drug Administration,
1401 Rockville Pike, suite 200N,
Rockville, MD 20852-1448,
301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

Since its establishment in 1995, the pre-IDE program has been a successful resource for both medical device applicants and the FDA. Originally, this program was designed to provide applicants a mechanism to obtain FDA feedback on future IDE applications prior to their submission. Over time, the pre-IDE program evolved to include feedback on other device submission program areas, such as Premarket Approval (PMA) applications, Humanitarian Device Exemption (HDE) applications, and Premarket Notification (510(k)) Submissions, as well as to address questions related to whether a clinical study requires submission of an IDE. The purpose of this guidance is to update the pre-IDE program to reflect this broader scope and make important modifications to reflect changes in the premarket program areas as a result of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110-85). This guidance also broadens the scope of the program to include those devices regulated by CBER. Accordingly, FDA is changing the name for this program from the pre-IDE program to the Pre-Submission (Pre-Sub) program.

The main purpose of the Pre-Sub program remains the same as the pre-IDE program: to facilitate providing advice to applicants when they have specific questions during product

development and early protocol planning, about device studies that present significant risk(s) (SR) as well as non-significant risk(s) (NSR) or when developing protocols for clinical studies conducted outside of the United States to support future U.S. marketing applications (Ref. 1). Consequently, the Pre-Sub program can provide an efficient path from device concept to market while facilitating the Agency's goal of meeting FDAAA and Medical Device User Fee Act of 2008 (MDUFA II) review milestones.

The Pre-Sub program has also faced several challenges, and the guidance is intended to address these challenges and improve the Pre-Sub program by: (1) Describing the types of information that FDA would recommend submitting in order to get the best possible feedback from FDA; (2) outlining the process by which FDA meetings should be scheduled; and (3) explaining the Agency's expectations regarding advice given during the Pre-Sub process.

This guidance outlines clear recommendations for sponsors and for FDA staff and managers as well as expected timeframes for scheduling meetings. FDA intends to provide the best possible advice in accordance with the information provided, ensure it is captured accurately in the meeting minutes drafted by the sponsor, and commit to that advice unless the circumstances sufficiently change such that our advice is no longer applicable, such as when a sponsor changes the intended use of their device after we provide feedback. It is also our intention to hold timely meetings with appropriate staff and managers present, if resources permit. However, both our ability to provide advice and to hold timely meetings are dependent on our receiving the necessary information in advance of the meeting.

In addition, this guidance also describes the procedures that CDRH and CBER intend to follow when industry representatives or application sponsors request a meeting with review staff, either as the preferred method of feedback in response to a Pre-Sub, or to discuss an existing

regulatory submission. This guidance also recommends how to prepare for meetings with FDA staff. FDA plans to revise the document as necessary to reflect any MDUFA III agreements.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on Medical Device Pre-Submissions and Meetings with CDRH and CBER Staff. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive "Medical Devices: Pre-Submissions and Meetings with FDA Staff," you may either send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1677 to identify the guidance you are requesting. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>; a search capability for all CBER guidance documents is available at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>. Guidance documents are also available at <http://www.regulations.gov>.

IV. Paperwork Reduction Act of 1995

Under the PRA (44 U.S.C. 3501–3502), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or

sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Draft Guidance for Industry and Food and Drug Administration Staff; Medical Devices:

The Pre-Submission Program and Meetings with FDA Staff

This draft guidance describes the Pre-Submission program for medical devices reviewed in CDRH and CBER. The guidance provides recommendations regarding the information that should be submitted in a Pre-Submission Package and procedures that should be followed for meetings between CDRH and CBER staff and industry representatives or application sponsors. When final, this document will supersede “Pre-IDE Program: Issues and Answers–Blue Book Memo D99-1” dated March 25, 1999.

A Pre-Submission is defined as a formal written request from an applicant for feedback from FDA to be provided in the form of a formal written response or, if the manufacturer chooses, a meeting or teleconference in which the feedback is documented in meeting minutes. A Pre-Submission is appropriate when FDA's feedback on specific questions is necessary to guide product development and/or application preparation. The proposed collections of information are necessary to allow the Agency to receive Pre-Submission Packages in order to implement this voluntary submission program.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Submission of Information for Pre-Submission Program	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Respondent (in hours)	Total Hours
CDRH	2465	1	2465	137	337,705
CBER	79	1	79	137	10,823
Total	2544	1	2544	137	348,528

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Respondents are medical device manufacturers subject to FDA's laws and regulations. FDA estimates that it will receive approximately 2544 pre-submission packages annually. The Agency reached this estimate by reviewing the number of submissions received by the Agency under the Pre-IDE program over the past 10 years. Based on FDA's experience with the Pre-IDE program, FDA expects the Pre-Submission program to continue to be utilized as a viable program in the future and expects that the number of pre-submission packages will increase over its current rate and reach a steady state of approximately 2544 submissions per year.

FDA estimates from past experience with the Pre-IDE program that the complete process involved with the program takes approximately 137 hours. This average is based upon estimates by FDA administrative and technical staff that is familiar with the requirements for submission of a Pre-Submission and related materials, have consulted and advised manufacturers on these requirements, and have reviewed the documentation submitted.

Therefore, the total reporting burden hours is estimated to be 348,528 hours.

Table 2.--Estimated Annual Reporting Burden¹

No. of Respondents	Total Burden Hours Annualized	Hourly Wage Rate	Total Cost Annualized
2544	137	\$150	\$52,279,200

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The average to industry per hour for this type of work is \$150, resulting in a cost of \$20,550 per respondent. The estimated submission cost of \$20,550 multiplied by 2544 submissions per year equals \$52,279,200, which is the aggregated industry reporting cost annualized.

This draft guidance also refers to previously approved information collections found in FDA regulations. The collections of information in 21 CFR part 803 are approved under OMB control number 0910-0437; the collections of information in 21 CFR part 807, subpart E is approved under OMB control number 0910-0120; and the collections of information in 21 CFR part 812 are approved under OMB control number 0910-0078.

V. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES), either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in

brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VI. References

The following references have been placed on display in the Division of Dockets Management (see Comments) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

1. Please see 21 CFR 812.3(m) and FDA's webpage on Clinical Trials, available at www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm

Dated: July 9, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-17078 Filed 07/12/2012 at 8:45 am; Publication Date: 07/13/2012]